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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/640,366	08/13/2003	Michael D. DeGould	112559.00002	8438

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/640,366	DEGOULD, MICHAEL D.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2006*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment filed May 8, 2006. All rejections have been withdrawn unless stated below. Claims 1-24 are rejected.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Declaration filed under 37 CFR 1.132

The Declaration under 37 CFR 1.132 filed May 8, 2006 is insufficient to overcome the rejection of claims 1-24 based upon the Scope of Enablement rejection under 35 USC § 112 and the Obviousness rejection under 35 USC § 103 as set forth in the last Office action because: the Declaration recites the compositions of the reference encompasses a sponge that does not meet the limitation of the claims such as flowability. Although this is one preferred embodiment of the reference, the reference also discloses the compositions may be a gel as reciting in col. 4, lines 19-25. The Declaration does not address this disclosure or differentiate how the gels that may be formulated from the gels are different from the instant claims. In regards to the Scope of Enablement rejection, the Declaration recites the pain may be treated but does not recite it can be prevented.

Claims

Claim Rejections - 35 USC § 112 – Scope of Enablement

Claims 1-24 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the prevention of alveolar osteitis. The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with these claims. The rejection is maintained.

Applicant argues by referencing M.P.E.P. § 2164.03 and notes " the more predictable the art is, the less information needs to be explicitly stated in the specification". Applicant further points out in the specification where it is described how to make and use the wound dressing. A Declaration by the Inventor is attached and in item 3 of the Inventor's Declaration, the Inventor explains the predictability of the prevention of alveolar osteitis and pain in the art. Based on this, it is submitted that specific examples regarding the prevention of alveolar osteitis and pain are not required in the specification to meet the enablement requirement. Applicant asserts the prevention of alveolar osteitis and pain are predictable in this art. This argument is not persuasive.

The rejection made is a rejection against the use of the term "prevention". The word "treatment" or phrase "inhibiting the occurrence" is suggested and would provide Applicant with the patent coverage for which they seek. In regards to where in the specification it is disclosed how to make and use the invention is moot because the

rejection is not made based on this. Furthermore, in regards to the Declaration, the Inventor recites how pain has been treated but does not prove that pain does not occur. In order to prevent pain, one must administer a compound that stops the pain from occurring. Usually a compound is given to mask the pain so that the patient cannot feel the pain but it does not stop the pain from occurring. Furthermore, when the medicine wears off, the patient starts to feel the pain as an indication to take more medicine, which means the medicine did not prevent the pain it inhibited the onset or masked the pain. In regards to preventing alveolar osteitis, there is lack of evidence in the specification or the declaration that shows using this will stop alveolar osteitis from occurring. Applicant would have to make a showing that once the treatment is performed the alveolar osteitis does not occur in the near or distant future.

Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 14-15, 18 and 21are rejected under 35 U.S.C. 102(b) as being anticipated by Higashi et al. (US Patent No. 4,906,670).

Higashi et al. disclose pharmaceutical compositions for treatment of periodontal disease. The compositions comprise atelocollagen and a cross-linking agent (col.3, lines 40-42). The compositions may be in the form of a gel, ointment or film (col. 3, lines

23-25), encompassing claim 21. In regards to the compositions being syringable, since the compositions may be in the form of a gel or ointment they may be extruded (see claim 1) from a source such as a syringe. Atelocollagen exhibits no antigenicity since the telopeptide chain responsible for immuno-activity has been removed; has a good affinity to vital tissues; stimulates bio-synthesis or metabolism of collagen; has an action to accelerate the healing of wounded connective tissues and formation of epitherial tissues; and is capable of being easily modified by, for example, formation of cross linkage by the use of chemical agents such as glutaraldehyde, or irradiation of ultraviolet light or rays, whereby the release rate of active ingredients can be easily controlled (col. 3, lines 43-56). The intended use of the wound dressing compositions carries no weight in determining the patentability of the instant claims because the compositions disclosed by the reference comprise substantially the same compounds, i.e., comprising atelocollagen and a cross-linking agent, are substantially the same as the compositions disclosed and claimed by the Applicant. Accordingly, in regards to the intended use, one would have reasonably expected that the compositions of the reference have substantially the same properties, treating alveolar osteitis and pain following tooth extraction of jaw cyst removal, as the applicant's compositions, since the compositions of the reference and the compositions of the instant claims are substantially the same. The reference anticipates the instant claims insofar as it discloses a composition comprising atelocollagen and a cross-linking agent.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 1-24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes et al. (US Patent No. 5,972,366) in view of Wallace et al. (US Patent No. 6,063,061). The rejection is maintained in regards to claims 1-2, 4, 8, 11-13, 15, 18 and 21-24. The rejection is withdrawn in regards to claims 3, 5-7, 9-10, 14, 16-17 and 19-20.

Applicant argues Haynes describes a fibrous carrier matrix with a pharmaceutical composition. Applicant quotes "preferably the carrier is fibrous, such as a fabric dressing and suture or a cross-linked solid foam adsorbable implant". Examples used are Gelfoam brand absorbable gelatin sterile sponges and Surgicel Absorbable Hemostat. Throughout the patent, Haynes describes a sponge material. The Inventor's Declaration explains collagen sponges are not flowable, lack any chemical or mechanical adhesive ability, and have only a 12 to 36 hour residence time in the oral cavity. As a result, collagen sponges are unable to achieve the intimate flow into bone interstices to provide resilient, long lasting barrier to the oral environment. Independent claims 1 and 12 require a "flowable" dressing. Thus all of the limitations of independent claims 1 and 12 are not shown or suggested in Haynes. Applicant argues in regards to Wallace that a prima facie case of obviousness cannot be established using the Wallace patent. The Office Action contends that Wallace suggests liquefying the Haynes device. It is submitted that this modification would change the principle operation of the Haynes device. In other words, by liquefying the Haynes device, it could not be cut and worked as described in the Haynes patent. This argument is not persuasive.

Although the ultimate preferred embodiment or material for the compositions is a sponge, the reference discloses a preferred carrier in the compositions may also be a gel. The materials that may be used as the carrier materials include crosslinked collagen or gelatin (col. 4, lines 23-25). A gel is flowable[1] and is the type of material recited in claim 11. In regards to the gel, Wallace shows how the composition can be delivered. When the composition is a gel it would not need to be cut and worked as described in the Haynes patent, it can be extrude to the cite with a syringe.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 6-7, 9-10, 16-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes et al. (US Patent No. 5,972,366) in view of Langer et al. (US 6,224,893).

Haynes et al. disclose a method of making an implants for implantation in the bone. The material contains a drug that upon application to a surgical site or wound is released to the surrounding tissue. The implant is used in surgical or dental procedures to provide pain relief, to control inflammation, infection and bleeding, to accelerate tissue or bone regrowth (col.3, lines 15-35). The resulting product can be introduced into tooth sockets after tooth extraction for drug delivery. The material can be removed days after surgery or a gum flap can be sewn over it, which will eventually be resorbed (col.11, lines 54-62). The compositions are made of collagen, gelatin, and oxidized cellulose (col. 4, lines 24-29). The compositions may be formulated into a gel, which is

[1] Answers.com, http://www.answers.com/gel&r=67, Feb. 2005, entire document

a flowable material (see footnote 1). The carrier may be sized and shaped in any manner suitable for the particular body cavity or tissue to which it will be applied. For implantation, the carrier matrix should be biodegradable and non-allergenic (col.5, lines 23-37). The reference differs from the instant claims insofar as it does not disclose the crosslinking agent is copper.

Langer et al. is used as a general reference and discloses collagen materials may be cross-linked with metal cations such as copper. The reference differs from the instant claims insofar as it does not disclose the compositions are used to treat alveolar osteitis and pain following tooth extraction.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder,* 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used the copper cations as cross-linking agents in the compositions of the primary reference motivated by the desire to use a compound for its known function as supported by cited precedent.

2) Claims 6-7, 9, 16-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes in view of Geistlich et al. (US 5,573,771).

The primary reference, Haynes et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose peroxides as the cross-linking agent.

Geistlich et al. disclose peroxides[2] are used as cross-linking agents for collagen and gelatin compounds (col. 2, lines 28-31). The reference differs from the instant claims insofar as it does not disclose the compositions are used to treat alveolar osteitis and pain following tooth extraction.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used peroxides as cross-linking agents in the compositions of the primary reference motivated by the desire to use a compound for its known function as supported by cited precedent.

3) Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes et al. (US Patent No. 5,972,366) in view of Higashi et al. (US Patent No. 4,906,670).

[2] Hydrogen peroxide cross-links collagen (Dalmasso et al. US 5,788,941, col. 5, lines 19-25).

The primary reference, Haynes et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose atelocollagen as the collagen used in the compositions.

The secondary reference, Higashi et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose the compositions treat alveolar osteitis and pain following tooth extraction.

It would have been obvious to one of ordinary skill in the art to have used atelocollagen as the collagen in the compositions of the primary reference motivated by the desire to use a collagen derivative that exhibited no antigenicity; has a good affinity to vital tissues; stimulates bio-synthesis or metabolism of collagen; has an action to accelerate the healing of wounded connective tissues and formation of epitherial tissues; and is capable of being easily modified by, for example, formation of cross linkage by the use of chemical agents such as glutaraldehyde, or irradiation of ultraviolet light or rays, whereby the release rate of active ingredients can be easily controlled, as disclosed by the secondary reference.

4) Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes et al. (US Patent No. 5,972,366) in view of Higashi et al. (US Patent No. 4,906,670) as applied to claim 3 above, and further in view of Geistlich et al. (US 5,573,771).

The primary and secondary references, Haynes et al. and Higashi et al., are discussed above. The references differ from the instant claims insofar as they do not disclose the compositions or methods having peroxides as cross-linking agents.

The tertiary reference, Geistlich et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose the compositions are used to treat alveolar osteitis and pain following tooth extraction.

It would have been obvious to one of ordinary skill in the art to have used peroxides as cross-linking agents in the compositions of the primary reference motivated by the desire to use a compound for its known function as supported by cited precedent. See *Sinclair & Carroll Co. v. Interchemical Corp.*, *In re Linder* and *In re Dial* cited above.

Claims 1-24 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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